

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF PUERTO RICO**

Jeanette Perez Maceira, et al.,
Plaintiffs,
v.

Customed, Inc. et al.,
Defendants.

Case No. 3:23-cv-1445

**Balchem Corporation's (Balchem) Response to Plaintiffs' Objections to Magistrate's
Report and Recommendation Dismissing Plaintiffs' Claims**

Introduction

Plaintiffs succinctly state what this case is about in the first line of their Objections to Magistrate Giselle López-Soler’s Report and Recommendation, ECF No. 109 (“Objections”): “This case involves ethylene oxide (‘EtO’) emissions from sterilization facilities in Puerto Rico[.]” Objections at 1. Since initiating their lawsuit in August 2023, Plaintiffs have filed three different versions of their Complaint against Medtronic PR, Inc., Customed, Inc., Edward Lifesciences Technology Sarl, Steri-Tech, Inc. (“Sterilizer Defendants”) and Balchem (a product supplier),¹ attempting to hold Balchem responsible for alleged air emissions of EtO from four different medical sterilization facilities in Puerto Rico. But Balchem does not own or operate these medical sterilization facilities or emit EtO.

After nearly two years of litigation, the Magistrate issued a carefully drafted, thoughtful, and comprehensive Report and Recommendation in May 2025, ECF No. 104 (“R&R”), that examined all of the claims and arguments raised by the parties, and recommended dismissal of all claims against Balchem. Plaintiffs’ Objections do not identify any legal errors or omissions in the Magistrate’s carefully considered decision dismissing Balchem. In the absence of a basis for objecting to the Magistrate’s conclusions, Plaintiffs raise factual allegations that were not included in the third version of Plaintiffs’ Complaint, and legal arguments omitted from their nearly fifty-page omnibus Opposition. This last-ditch repleading strategy cannot save Plaintiffs’ claims against Balchem from dismissal. All of Plaintiffs’ claims and arguments outside the scope of the motion to dismiss briefing reviewed by the Magistrate have been waived. But even if the Court considered all the new alleged facts and arguments that Plaintiffs include in their Objections for the first time, the Court’s conclusion should still be the same. Plaintiffs cannot change the facts or the law to fit

¹ Plaintiffs also brought suit against Mays Chemical Company (“Mays”), an alleged distributor. Plaintiffs do not object to the dismissal of Mays.

their negligence, nuisance, design defect, or failure to warn theories. Balchem did not emit EtO. Balchem is not liable for Plaintiffs' alleged injuries. Plaintiffs should not be given another chance to reinvent their case against Balchem. Accordingly, the Court should adopt the Magistrate's decision and dismiss all of Plaintiffs' claims against Balchem with prejudice.

Background

In August 2023, Plaintiffs filed suit against the Sterilizer Defendants, Balchem, and Mays alleging various causes of action including negligence, nuisance, unjust enrichment,² design defect, and failure to warn. Following separate motions to dismiss by the Sterilizer Defendants, Steri-Tech, Balchem, and Mays in January 2024, Plaintiffs filed an amended complaint and added multiple plaintiffs including Daniel Leslie as a putative class representative in early February 2024. ECF No. 65. Mr. Leslie and potentially other newly added plaintiffs were mistakenly copied into the complaint from a completely different case from a different state. *Id.* On February 29, 2024, Plaintiffs filed a Corrected Amended Complaint, ECF No. 74 ("Complaint" or "Compl."),³ which is the operative complaint in this case. Defendants filed a second round of motions to dismiss in April 2024. ECF Nos. 75, 76, 79. On May 29, 2024, Plaintiffs finally filed an omnibus Opposition to all the motions to dismiss, ECF No. 83 ("Opposition" or "Opp."), to which Defendants replied on June 20, ECF Nos. 84, 87. On May 23, 2025, the Magistrate issued an Omnibus Report and Recommendation narrowing the claims against the Sterilizer Defendants and dismissing all claims against Balchem and Mays. ECF No. 104. On June 16, Plaintiffs filed Objections to the Report

² Plaintiffs do not appear to object to the Magistrate's recommendation of dismissal of their unjust enrichment claim. R&R at 20–21.

³ Although Plaintiffs had agreed to limit the scope of their amendments to correct the deficiencies in the Amended Complaint, the Corrected Amended Complaint (the third version of the Complaint) included a number of new substantive allegations not previously included in the Amended Complaint, including allegations relating to a subsidiary of Balchem in Missouri. ECF No. 75, Motion to Dismiss at 6, n.8.

and Recommendation raising numerous new factual allegations and legal arguments not previously addressed in their Complaint or Opposition. ECF No. 109.

Argument

A. Plaintiffs' Objections Focus Almost Entirely on New Arguments Not Considered by the Magistrate.

Plaintiffs raise numerous allegations and arguments against Balchem for the first time in their Objections. Virtually all of the arguments and case law cited by Plaintiffs in their Objections appear nowhere in their Complaint or Opposition. Objections at 2, 9–19.⁴ None of the new allegations and arguments are properly before the Court: “The law is clear that when a dispositive motion is heard before a magistrate judge, the movant must make all her arguments then and there, and cannot later add new arguments at subsequent stages of the proceeding.” *Cherox Inc. v. Tip Top Constr. Corp.*, 175 F. Supp. 3d 1, 3 (D.P.R. 2016) (citing *Maurice v. State Farm Mut. Auto. Ins. Co.*, 235 F.3d 7, 10–11 (1st Cir. 2000)). While it is true that the Court may conduct a *de novo* review of the Magistrate’s decision under Federal Rule of Civil Procedure 72(b), that review is

⁴ As only one example, Plaintiffs allege for the first time, without any supporting facts, that Balchem provided “safety materials” that “instructed sterilization operators and workers to ventilate EtO into the air to mitigate the hazards of toxic exposures and explosions within the sterilization facility.” *Id.* at 2. To the extent Plaintiffs’ new allegations refer to the EtO safety data sheet (“SDS”), their emissions claims are not plausible. The SDS section on ventilation states: “Emission controls must be in compliance with Federal, State, and local regulations.” ECF No. 75, Motion to Dismiss, Exh. 2. The allegations may also be referring to a direction for use on Balchem’s 100% EtO label which states: “In order to reduce ambient levels of ethylene oxide, lengthy facility aeration is encouraged.” *Id.*, Exh. 1. That direction was mandated by EPA in March 2008. The direction refers to reducing worker exposures to EtO inside facilities, not encouraging emissions of EtO to the atmosphere. See U.S. EPA, *Reregistration Eligibility Decision for Ethylene Oxide*, at 53, table (Mar. 31, 2008) (“In order to reduce ambient levels of ETO, lengthy facility aeration is encouraged.”), <https://archive.epa.gov/pesticides/reregistration/web/pdf/ethylene-oxide-red.pdf>. Balchem could not reregister and supply EtO to medical sterilization facilities without adding this specific label change from EPA. *Id.* at 49 (“**In order to be eligible for reregistration**, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table **describes how language on the labels should be amended.**” (emphasis added)). See *Gent v. CUNA Mut. Ins.*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (allowing judicial notice of official government documents including websites).

necessarily limited to “any part of the magistrate judge’s disposition that has been properly objected to.” Fed. R. Civ. P. 72(b) (emphasis added). Plaintiffs are not entitled to the Court’s consideration of theories and arguments never raised in their Complaint or Opposition. *See Cortes-Rivera v. Dep’t of Correction & Rehab. of P.R.*, 617 F. Supp. 2d 7, 14 (D.P.R. 2009) (“[N]ew arguments, or newly raised evidence, are to be excluded as reconsideration arguments originally available to movant at the time of the submission to the magistrate judge.”), *aff’d*, 626 F.3d 21 (1st Cir. 2010). Following multiple opportunities to amend their Complaint and file opposition briefs, Plaintiffs have now effectively waived the arguments raised for the first time in their Objections.

While Plaintiffs’ new factual allegations and legal arguments reveal the significant deficiencies in their Complaint and Opposition, Plaintiffs’ strategy appears aimed at obtaining another chance to amend their Complaint. The Court should not allow Plaintiffs to circumvent the Magistrate’s decision or allow them another opportunity to reset the clock and replead their unmeritorious claims. *See Miller v. Tyler Louthan*, No. 22-01538, 2024 WL 1230255, at *11 (D.P.R. Mar. 22, 2024) (dismissing claims in amended complaint with prejudice because plaintiff failed to plead necessary facts, and denying leave to amend where new arguments intended to salvage claims were raised for the first time in plaintiff’s objection to the magistrate judge’s report and recommendation). As in *Tyler Louthan*, Plaintiffs also repeatedly invoke their desire for additional discovery in order to find additional facts that might bolster their claims. Objections at 11, 18. The Court should “not grant Plaintiff leave to amend [their] Amended Complaint so that [they] may justify a fishing expedition ‘aimed at finding the cause of action that [they] failed to properly state in [their] Amended Complaint.’” *Tyler Louthan*, 2024 WL 1230255, at *11; *see also Lahens v. AT&T Mobility P.R., Inc.*, No. 18-1776, 2019 WL 1149923, at *3 (D.P.R. Mar. 11, 2019) (“Plaintiff is essentially asking this court to place the cart before the horse by requesting discovery as a means of curing the initial complaint’s fatal lack of development. . . . In the future, Plaintiff’s

counsel would do well to think twice before raising such blatantly underdeveloped arguments.”). The claims against Balchem in the Amended Complaint should be dismissed with prejudice.

B. Plaintiffs Cannot Plead a Negligence Claim Against Balchem.

Plaintiffs cannot plead a negligence claim⁵ against Balchem as a matter of law. As the Magistrate held, Balchem did not have a duty of care in this case. R&R at 16. The only duties that Plaintiffs identified in their Complaint and Opposition are an alleged duty to train Sterilizer Defendants’ employees and a purported duty tied to Balchem’s role as EtO’s product registrant. The Magistrate rejected both arguments. R&R at 16–17. First, Plaintiffs cannot dispute that as a matter of law, the obligation to train employees regarding the use and handling of EtO rests entirely on the Sterilizer Defendants. 29 C.F.R. § 1910.1047(j)(1)(iii) (“Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS [Hazard Communication Standard] and paragraph (j)(3) of this section.”); R&R at 16–17. Second, Plaintiffs do not, and cannot, identify any special legal duty tied to Balchem’s status as a product registrant for EtO. R&R at 17.

Plaintiffs argue for the first time in their Objections that Balchem assumed a duty of care by providing training to Sterilizer Defendants on the handling of EtO. Objections at 12. The claim appears nowhere in Plaintiffs’ Complaint or Opposition, and therefore was not considered by the Magistrate. The Court should not consider it now. *Cortes-Rivera*, 617 F. Supp. 2d at 14. But even if the Court considers this new argument, it still cannot save Plaintiffs’ negligence claim.

In support of their argument that Balchem assumed a duty, Plaintiffs argue for the first time that Balchem had a duty of care under Restatement (Second) of Torts Section 324A. But Plaintiffs cite no authority that Restatement Section 324A has been adopted in Puerto Rico. Plaintiffs cite

⁵ Plaintiffs do not appear to dispute dismissal of their Gross Negligence claim. R&R at 17.

no Puerto Rico law, and there is no indication Puerto Rico applies Section 324A or Puerto Rico otherwise imposes an assumed duty of care like the one described by Plaintiffs. *See Jimenez-Ruiz v. Spirit Airlines, Inc.*, 794 F. Supp. 2d 344, 351 (D.P.R. 2011) (“As a general rule, an individual is only liable for his own acts or omissions A third party can only be liable for the acts or omissions of others when clearly specified in the law.”) (citations and quotations omitted). Second, Plaintiffs cite previously unmentioned Massachusetts case law for the proposition that Balchem is potentially liable for failing to train Sterilizer Defendants’ employees. Objections at 13; *see Brettel v. Omron Sci. Techs., Inc.*, 302 F. Supp. 3d 460, 467 (D. Mass. 2018). Notably, the *Brettel* case involved the alleged duty owed by a third-party safety consultant hired for the express purpose of identifying workplace hazards, not a product supplier. Plaintiffs continue to overlook federal OSHA law and Puerto Rico law that states that the duty to train employees on chemical safety is the sole responsibility of employers, not a product supplier like Balchem. 29 C.F.R. § 1910.1047; *Modern Cont'l Constr. Co., Inc. v. OSHA Review Comm'n*, 305 F.3d 43, 49 (1st Cir. 2002); *Vulcan Tools of P.R. Inc. v. Makita U.S.A., Inc.*, No. 89-148(RLA), 1993 WL 719565, at *8 (D.P.R. Sept. 1, 1993).

Finally, Plaintiffs now argue that Balchem’s activity was part of “an ongoing effort by Balchem to influence the operational conduct of EtO sterilizers and support product sales.” Objections at 14.⁶ These allegations were not included in the Complaint, and therefore the Court need not credit them. But even if these new allegations had been included in the Complaint, they still would not change the outcome here. The Magistrate already considered and rejected much more specific allegations regarding Balchem’s purported influence over the sterilization facilities’ operations. R&R at 16. Because Plaintiffs cannot allege a duty where none exists as a matter of

⁶ Plaintiffs further argue that “it is entirely foreseeable that Sterilizer Defendants . . . relied on Balchem’s expertise and instruction in developing and executing their handling protocols.” *Id.*

law, further amendment of the Complaint would be futile, and Plaintiffs' negligence claim should be dismissed with prejudice. *See Strojnik v. Int'l Hosp. Enters., Inc.*, No. 19-1714, 2020 WL 12719129, at *4 (D.P.R. Oct. 30, 2020) (dismissing negligence claim with prejudice on Rule 12 motion and denying leave to amend "as a fallback position" (internal citation omitted)).

C. Plaintiffs Cannot Plead Nuisance Claims Against Balchem.

The Court should affirm the Magistrate's decision that Plaintiffs cannot plead a nuisance claim against Balchem as a product supplier. Even Plaintiffs previously admitted Balchem did not own or operate the medical sterilization facilities in Puerto Rico that allegedly emitted EtO. Compl. at 8 ¶¶ 29–31, 35. As clearly described by the Magistrate, a "cause of action" for nuisance "has a dual purpose: the abatement of the nuisance and the compensation of damages caused by the nuisance." R&R at 18 (citing *Ortega Cabrera v. Tribunal Superior*, 101 D.P.R. 612, 1 P.R. Offic. Trans. 842, 848 (1973)). The Magistrate determined that Plaintiffs cannot sustain a nuisance claim in this case against Balchem "because it is undisputed that Balchem and Mays do not operate the sterilizing facilities in Puerto Rico" and "they would be unable to abate the purported nuisance—the emission of EtO by the Sterilizer Defendants." *Id.* at 19. The Magistrate also determined that the "Amended Complaint is devoid of any specificity on how exactly the EtO emissions . . . affected Plaintiffs' property or welfare or how their personal enjoyment has been, or continues to be, lessened by the nuisance." *Id.* (emphasis added). In other words, Plaintiffs also have not pleaded any injury or damages.

In their Opposition, Plaintiffs devoted only a single paragraph supporting their nuisance claims against Balchem and did not cite a single case supporting their position that a chemical supplier could be liable for a nuisance related to emissions from a site it does not own or operate under Puerto Rico law. Opp. at 26. Accordingly, the Court should ignore much of the nearly three

pages of argument that Plaintiffs present in their Objections for the first time including Massachusetts and California case law. Objections at 9–12.

Even if the Court considers the new arguments and law cited for the first time in the Objections, the Magistrate’s well-reasoned analysis still disposes of these claims against Balchem under Puerto Rico law. R&R at 18–20. Plaintiffs attempt to re-style their allegations, but they have nothing more to add to their existing pleadings that can change the outcome. Objections at 10. The Magistrate already considered Plaintiffs’ various arguments regarding Balchem’s alleged “training” of Sterilizer Defendants on the “handling” of EtO and deemed these allegations “insufficient to assert a nuisance claim.” R&R at 19. Despite Plaintiffs’ efforts to conflate Balchem’s alleged training with EtO emissions from facilities, Plaintiffs do not, and cannot, allege that Balchem had any control over EtO emissions from sterilization facilities it does not own or operate.

The new cases Plaintiffs cite under Massachusetts and California law to overcome these inconvenient facts are irrelevant. Objections at 10–11. Notably, in the Massachusetts case, the nuisance claims were not even maintained against the chemical manufacturer defendant. *See Ryan v. Greif, Inc.*, 708 F. Supp. 3d 148, 174–75 (D. Mass. 2023). In the California case, the district court held that plaintiffs had pleaded facts supporting opioid manufacturers’ affirmative participation in creating a drug epidemic. *City & County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 675–76 (N.D. Cal. 2020). No such facts alleging Balchem’s actual control over EtO emissions at facilities it does not own or operate have been pleaded here. Moreover, EtO is an irreplaceable chemical used to sterilize half the medical equipment in the United States, which EPA and FDA acknowledge and continue to support. Motion to Dismiss at 8. Balchem supplied Sterilizer Defendants a necessary medical sterilant, not a potentially addictive opioid.

As the Magistrate concluded, Puerto Rico law provides that the absence of evidence of control over the source of an alleged nuisance (including the ability to abate the nuisance) bars such a claim against a product supplier. *See Muns. of Bayamón v. Exxon Mobil Corp.*, No. 22-1550, 2025 WL 600430, at *42 (D.P.R. Feb. 20, 2025) (recommending dismissal of nuisance claims where oil and gas companies were not present and did not operate facilities in Puerto Rico). The Court should dismiss Plaintiffs' nuisance claims against Balchem with prejudice because further amendment of their Complaint would be futile. *See Tyler Louthan*, 2024 WL 1230255, at *10 (dismissing claim with prejudice on Rule 12 motion where amended complaint was likewise "devoid" of factual allegations). Because Plaintiffs cannot further amend the Complaint to plead viable nuisance claims against a product supplier under Puerto Rico law, the claims should be dismissed with prejudice.

D. Plaintiffs Cannot Allege Design Defect Claims.

The Court should adopt the Magistrate's dismissal of the design defect claims against Balchem and dismiss Plaintiffs' design defect claims with prejudice. Plaintiffs argue that the Magistrate "mischaracterizes" their design defect allegations in the Complaint. Objections at 15. But it is the Plaintiffs who mischaracterize their own allegations and the law.

The Magistrate dismissed the design defect claims on two grounds. First, the Magistrate dismissed the design defect claims because challenging the use of the 100% EtO product is not a viable design defect claim. In the Complaint, Plaintiffs allege that any use of EtO in the 100% EtO product is a design defect. Compl. at 30 ¶ 147 ("Defendants' EtO mixture and EtO-containing products as described herein constituted an unreasonably and inherently dangerous design of such products in that they contained EtO . . ."). As the Magistrate rightly concludes, Plaintiffs' argument that Balchem should have supplied an alternative product to the Sterilizer Defendants is not a viable design defect claim. R&R at 23; *see Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir.

2016) (“[T]he focus of the reasonable alternative design inquiry . . . requires the plaintiff to show that the product in question could have been more safely designed, not that a different product was somehow safer.”); *Ayala v. Kia Motor Corp.*, 633 F. Supp. 3d 555, 569–70 (D.P.R. 2022).⁷ Second, even if the Plaintiffs had pleaded an alternative design for EtO, the Magistrate concluded that Plaintiffs still do not plead proximate cause. R&R at 23–24; *Ayala*, 633 F. Supp. 3d at 569. Plaintiffs fail to plead that their alleged injuries from EtO had anything to do with a potential design defect.

Once again, Plaintiffs raise new arguments in their Objections that the Court can simply ignore as waived. Objections at 15–16. But, if the Court considers these new arguments, they should still be summarily rejected for the same reasons the Magistrate recommended dismissal of Plaintiffs’ design defect claims. Plaintiffs jettison their primary argument that Balchem should not have supplied EtO altogether and now argue that the 100% EtO “lacked fundamental safety modifications.” Objections at 15. Apparently, these alleged “safety modifications” amount to the addition of an odorant. *Id.* at 15–16. As previously mentioned in Balchem’s Motion to Dismiss, this argument fails because the addition of an odorant to 100% EtO would create a new product subject to EPA and FDA approval as a sterilant. Motion to Dismiss at 16–17.⁸

⁷ Moreover, as the EPA sources cited in Plaintiffs’ own Complaint demonstrate, there are no viable substitutes for EtO for use in the sterilization of life-saving medical equipment. Compl. at 14 ¶ 57 n.9 (referencing EPA’s Interim Registration Review Decision, which states at page 28, “there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment”).

⁸ 100% EtO with a non-active ingredient odorant is a different chemical product with potentially, completely different properties (including different effectiveness as a medical sterilant) that require EPA evaluation prior to approval. 40 C.F.R. § 152.43. The use of an alternative formulation of EtO also would be considered a “novel sterilization method” by the FDA. U.S. FDA, *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, at 5 (Jan. 8, 2024), <https://www.fda.gov/media/74445/download>.

In their Objections, Plaintiffs argue that the addition of an odorant is feasible because Balchem sells products that are EtO mixtures. Objections at 16. While Plaintiffs are correct that Balchem sells products with varying amounts of EtO, each of those products are independently registered and approved for use by EPA and FDA as separate products.⁹ In other words, Plaintiffs have proved Balchem's point. Any EtO mixture is a different product subject to completely independent EPA and FDA approval, testing, and registration requirements. The addition of an odorant to 100% EtO would create yet another new product requiring EPA and FDA registration, testing, and approval under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").

Plaintiffs fail to explain in the Objections how their design defect claims are any different than the rejected design defect theory in *City of Philadelphia v. Lead Indus. Ass'n*, No. 90-7064, 1992 WL 98482, at *3 (E.D. Pa. Apr. 23, 1992), that the defendant should use zinc-based pigments instead of lead-based pigments in their product. As in *City of Philadelphia*, Plaintiffs assert that Balchem should have supplied a product to the Sterilizer Defendants with a different chemical formulation. R&R at 23. This is not a valid design defect theory.

Finally, as the Magistrate held, Plaintiffs have not pleaded any theory by which Plaintiffs can show that a design modification to 100% EtO could have proximately caused the injuries of Plaintiffs.¹⁰ A design defect claim "does not extend to every conceivable risk, since the manufacturer is not an absolute insurer for all injuries their product may cause." *Coqui Holdings, CRL v. Maderas 3C, LLC*, No. KLAN202200951, 2023 WL 5286421, at *8 (P.R. Ct. App. July

⁹ See U.S. EPA, *Pesticide Product and Label System*, <https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1> (exs. EPA Reg. Nos. 36736-4-35084 (80% Ethylene Oxide); 36736-2 (100% Ethylene Oxide)).

¹⁰ Even if feasible, the addition of an odorant could not have prevented emissions of EtO or changed the allegedly toxic nature of the EtO. Nor have Plaintiffs pleaded that an odorant could have feasibly been added in sufficient quantities to be detected up to four miles away from the medical sterilization facilities. Compl. ¶ 96.

18, 2023). Plaintiffs allege throughout the Complaint that the cause of Plaintiffs' alleged injuries was the emissions of EtO from Sterilizer Defendants' facilities and equipment. Compl. at 4 ¶ 2; 8 ¶ 35; 9 ¶¶ 37–41; 11–12 ¶¶ 43–46. As admitted by Plaintiffs, the design of 100% EtO did not cause Plaintiffs' alleged injuries. Because there is no theory under which the Plaintiffs can plead a design defect against Balchem, and an allegedly defective design could not have been the proximate cause of Plaintiffs' alleged injuries, the Court should dismiss the design defect claims with prejudice.

E. Plaintiffs' Admissions Bar Their Failure to Warn Claims.

The Court should adopt the Magistrate's decision dismissing Plaintiffs' failure to warn claims. The Magistrate correctly determined that Plaintiffs failed to allege that any potential defect in Balchem's product warnings could have caused their alleged injuries. R&R at 25 ("But Plaintiffs admit that Sterilizer Defendants were aware of EtO's effects, regardless of whether Balchem warned them or not."). Plaintiffs allege throughout the Complaint, and in the Opposition, that Sterilizer Defendants were "sophisticated corporations" that knew of the dangers of EtO, but they chose to ignore those dangers and emit EtO anyway. Compl. at 4 ¶ 2; 8 ¶ 35; 9 ¶¶ 37–41; 11–12 ¶¶ 43–46; Opp. at 38. After having repeatedly argued that any warning from Balchem would not have made a difference, Plaintiffs cannot have it both ways and allege that their injuries were caused by Balchem's failure to provide the Sterilizer Defendants a warning.

Once again, rather than addressing the Magistrate's well-reasoned conclusions, Plaintiffs' Objections attempt to shift the Court's focus to new arguments that appear nowhere in their Complaint or Opposition. Objections at 18. Plaintiffs argue for the first time that Balchem "could have lawfully updated its labeling to include clear emission mitigation instructions" under 40 C.F.R. § 152.46. *Id.* Plaintiffs further argue that such label changes would be permissible under 40 C.F.R. § 156.10(i). *Id.* The Court should ignore Plaintiffs' new arguments, which, like the others,

have been waived. But even if the Court accepts these new arguments, they still do not save Plaintiffs' failure to warn claims.

As discussed at length in Balchem's Motion to Dismiss, EPA reviews and approves all language on pesticide labels, including the label for EtO. Motion to Dismiss at 4 ("We [U.S. EPA] review pesticide product labels as part of the licensing/registration process **and must approve all** label language before a pesticide can be sold or distributed in the United States." (citing EPA website, emphasis added)). Contrary to Plaintiffs' arguments, Balchem would have no authority to add information to the "directions for use" of EtO on the product label without EPA approval. Plaintiffs are simply wrong on this point as a matter of law. 40 CFR § 156.70(c) ("[S]pecific statements pertaining to the hazards of the product and its uses must be approved by the Agency."). Changing the "directions for use" on EtO as Plaintiffs suggest to include additional warnings would require a label amendment under FIFRA and would not be within the discretion of Balchem.

Finally, Plaintiffs argue for the first time that their failure to warn claims were not merely based on product labeling, but also based on allegations of "deficient training, safety guidance, or omissions in operational instruction." Objections at 18. Once again, these particular allegations appear nowhere in Plaintiffs' Complaint.¹¹ Plaintiffs' new arguments are waived. But, again, even if they were considered, Plaintiffs still do not identify any specific deficiency in any of the warnings provided by Balchem. And, more importantly, having admitted that Sterilizer Defendants were already aware of EtO's effects, Plaintiffs still cannot establish that "the warning or instructions or the trainings provided by Balchem would have ameliorated their harm." R&R at 25. Plaintiffs cannot establish proximate causation on a failure to warn claim where the premise of

¹¹ Nor did the Magistrate have an opportunity to consider a 2025 decision from a New York court. *Id.*; see *In re MTBE Prods. Liab. Litig.*, No. 14-cv-6228, 2025 WL 1658444, at *6–7 (S.D.N.Y. Jun. 11, 2025) (applying Pennsylvania law).

their case is that the Sterilizer Defendants knew of the risks of EtO all along, but chose to ignore those risks. Compl. at 9–12, ¶¶ 37, 40, 43–46. Accordingly, the Court should dismiss the failure to warn claims with prejudice.

Conclusion

For the reasons set forth above, Balchem respectfully requests dismissal of the Complaint with prejudice.

Dated: July 10, 2025

Respectfully submitted,

/s/ Matthew D. Thurlow

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Certificate of Service

I hereby certify, that on July 10, 2025, this document was filed with the Court's CM/ECF system, which will simultaneously serve notice on all counsel of record to their registered email addresses.

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